

# DBL™ Leucovorin Calcium

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## Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

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### 1. Why am I using DBL Leucovorin Calcium?

DBL Leucovorin Calcium Tablet contains the active ingredient calcium folinate hydrate and DBL Leucovorin Calcium Injection contains the active ingredient calcium folinate. It is a type of Vitamin B used to treat some types of anaemia when they occur during pregnancy and infancy or caused by liver disease, inadequate food intake or poor food absorption. It may also be used to treat the toxic effects of some medicines.

For more information, see Section [1. Why am I using DBL Leucovorin Calcium?](#) in the full CMI.

## **2. What should I know before I use DBL Leucovorin Calcium?**

Do not use if you have ever had an allergic reaction to calcium folinate or any of the ingredients listed at the end of the CMI or if you have a type of anaemia caused by too little vitamin B12.

Talk to your doctor if you have any other medical conditions, have problems with your kidneys or have diarrhoea; if you take any other medicines or are pregnant or plan to become pregnant or are breastfeeding.

Discuss the need for any restrictions with food and drink with your doctor.

For more information, see Section [2. What should I know before I use DBL Leucovorin Calcium?](#) in the full CMI.

## **3. What if I am taking other medicines?**

Some medicines may interfere with DBL Leucovorin Calcium and affect how it works. It is especially important to tell your doctor if you are taking medicine to treat epilepsy.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

## 4. How do I use DBL Leucovorin Calcium?

Your doctor will decide what dose and how long you will receive DBL Leucovorin Calcium. This depends on the condition you are being treated for.

More instructions can be found in Section [4. How do I use DBL Leucovorin Calcium?](#) in the full CMI.

## 5. What should I know while using DBL Leucovorin Calcium?

<b>Things you should do</b>	<p>Ensure tablets are taken on an empty stomach.</p> <p>Tell your doctor if you are pregnant, trying to become pregnant or are breast-feeding.</p> <p>Tell any doctor you visit that you are taking DBL Leucovorin Calcium.</p> <p>Do not give your medicine to anyone else, even if they have the same condition as you.</p>
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<b>Things you should not do</b>	Do not stop taking this medicine or change the dose unless instructed by your doctor.
<b>Drinking alcohol</b>	No information available.
<b>Looking after your medicine</b>	Injection: This medicine is stored in a hospital at 2 - 8°C.  Tablet: Store below 25°C.

For more information, see Section [5. What should I know while using DBL Leucovorin Calcium](#) in the full CMI.

## **6. Are there any side effects?**

Side effects of this medicine include allergic reactions; lack of control of epilepsy, fits, convulsions or fainting; serious gastrointestinal problems; dehydration; sore mouth; symptoms of severe infection; abnormal bleeding; skin conditions with severe redness, blisters, peeling and bleeding; fever, fatigue, chills, feeling unwell; shortness of breath, dizziness, pale skin, cold hands and feet; rashes; nausea, vomiting, diarrhoea; depression, agitation or trouble sleeping.

For more information on these side effects, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.



# DBL™ Leucovorin Calcium (loo-koe-VOR-in)

**Active ingredient(s):** calcium folinate hydrate (tablet) and calcium folinate (injection)

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## Consumer Medicine Information (CMI)

This leaflet provides important information about using DBL Leucovorin Calcium. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using DBL Leucovorin Calcium.**

**Where to find information in this leaflet:**

- [1. Why am I using DBL Leucovorin Calcium?](#)
- [2. What should I know before treatment with DBL Leucovorin Calcium?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use DBL Leucovorin Calcium?](#)
- [5. What should I know while using DBL Leucovorin Calcium?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

## **1. Why am I using DBL Leucovorin Calcium?**

**DBL Leucovorin Calcium** is a type of Vitamin B and is used to treat:

- Some types of anaemia when they occur during pregnancy and infancy or caused by liver disease, inadequate food intake or poor food absorption.
- The toxic effects of some medicines such as methotrexate, fluorouracil and pyrimethamine.

## **2. What should I know before treatment with DBL Leucovorin Calcium?**

### **Warnings**

#### **Do not use DBL Leucovorin Calcium if:**

- you are allergic to calcium folinate, or any of the ingredients listed at the end of this leaflet.
- you have anaemia caused by low levels of red blood cells or genetically defective red blood cells due to a lack of Vitamin B12.

#### **Check with your doctor if you:**

- have problems with your kidneys
- have diarrhoea
- require food and drinks that have low acidity while being treated with DBL Leucovorin Calcium

- are taking epilepsy medication.

## **Pregnancy and breastfeeding**

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

### **3. What if I am taking other medicines?**

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

DBL Leucovorin Calcium may be given to you for the purpose of treating the toxic effects of certain other medications such as:

- Methotrexate, a medicine used to treat rheumatoid arthritis, psoriasis, inflammatory bowel disease or some cancers
- 5-fluorouracil (5-FU), a medicine used to treat some cancers
- Cotrimoxazole or pyrimethamine, medicines used to treat some infections

If you are being treated with any of these medicines and your doctor is not aware, it is critical that you tell them.

Some medicines and DBL Leucovorin Calcium may interfere with each other. These include:

- medicines used to treat epilepsy such as phenytoin, phenobarbitone, succinimides and primidone
- chloramphenicol, an antibiotic used to treat bacterial infections

**Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect DBL Leucovorin Calcium.**

## **4. How do I use DBL Leucovorin Calcium?**

### **How much to take**

Your doctor will decide what dose and how long you will receive DBL Leucovorin Calcium Injection and Tablet. This depends on the condition you are being treated for.

DBL Leucovorin Calcium Injection will be given to you by a doctor or nurse.

### **When to take DBL Leucovorin Calcium Tablet**

DBL Leucovorin Calcium Tablet should be swallowed with a full glass of water. It should be taken on an empty stomach, for example, at least half an hour before food or two hours after food. The tablet should be taken whole and not chewed or crushed.

## **If you forget to take DBL Leucovorin Calcium Tablet**

DBL Leucovorin Calcium Tablet should be taken regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you can, but do not take a double dose to make up for forgotten tablet.

**If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to.**

**Do not take a double dose to make up for the dose you missed.**

## **If you use too much DBL Leucovorin Calcium**

If you think that you have used too much DBL Leucovorin Calcium, you may need urgent medical attention.

### **You should immediately:**

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

**You should do this even if there are no signs of discomfort or poisoning.**

## **5. What should I know while using DBL Leucovorin Calcium?**

### **Things you should do**

**Tell your doctor if you are pregnant, trying to become pregnant or breast-feeding.**

Tell any doctor or any healthcare professional you visit that you are using DBL Leucovorin Calcium.

### **Things you should not do**

- Do not stop taking this medicine or change the dosage unless instructed by your doctor.

### **Driving or using machines**

Be careful before you drive or use any machines or tools until you know how DBL Leucovorin Calcium affects you.

### **Drinking alcohol**

**No information available.**

### **Looking after your medicine**

#### **DBL Leucovorin Calcium Solution for Injection**

Stored at the hospital, refrigerated at 2 - 8 °C. Do not freeze.

## **DBL Leucovorin Calcium Tablet**

Store below 25°C.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Do not use this medicine after the expiry date.

**Keep it where young children cannot reach it.**

### **Getting rid of any unwanted medicine**

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

## **6. Are there any side effects?**

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

## Side effects

Side effects	What to do
<ul style="list-style-type: none"><li>• Fever</li><li>• Nausea</li><li>• Vomiting</li><li>• Sore lips</li><li>• Depression, agitation or trouble sleeping</li><li>• Rashes</li></ul>	<b>Speak to your doctor or nurse if you have any of these side effects and they worry you.</b>

Side effects	What to do
<ul style="list-style-type: none"><li>• Signs of an allergic reaction including shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, rash, itching or hives on the skin</li><li>• Lack of control of epilepsy</li><li>• Fits or convulsions, and/or fainting</li><li>• Gastrointestinal problems which may include diarrhoea,</li></ul>	<b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b>

<b>Side effects</b>	<b>What to do</b>
<p>constipation, ulcers around the anus, blood in faeces (stools), stomach or gut pain/ cramps, bloating</p> <ul style="list-style-type: none"> <li>● Problems with your mouth including pus, ulcers, blisters, peeling or swelling, a burning feeling and trouble swallowing or talking</li> <li>● Fatigue with shortness of breath and dizziness</li> <li>● Pale skin with cold hands and feet</li> <li>● Symptoms of severe infection indicated by fever, cough, rash, swelling, diarrhoea, discomfort while urinating</li> <li>● Abnormal bleeding such as bruising easily, nose bleeds, bleeding gums, abnormal menstrual bleeding and severe fatigue</li> <li>● Skin condition with severe blisters and bleeding in the lips,</li> </ul>	

<b>Side effects</b>	<b>What to do</b>
eyes, mouth, nose and genitals	

## **Side effects**

<b>Side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"> <li>• Areas of skin that are red and painful, blister and peel, accompanied by fever, chills and feeling unwell</li> <li>• Redness, swelling or peeling of the palms or the soles of the feet.</li> </ul>	<p><b>Call your doctor straight away or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</b></p>

**Tell your doctor, nurse or pharmacist if you notice anything else that may be making you feel unwell.**

Other side effects not listed here may occur in some people.

## **Reporting side effects**

After you have received medical advice for any side-effects you experience, you can report side effects to the Therapeutic Goods Administration online at [www.tga.gov.au/reporting-problems](http://www.tga.gov.au/reporting-problems). By reporting side effects, you can help provide more information on the safety of this medicine.

**Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.**

## **7. Product details**

This medicine is only available with a doctor's prescription.

### **What DBL Leucovorin Calcium Injection contains**

<b>Active ingredient (main ingredient)</b>	calcium folinate
<b>Other ingredients (inactive ingredients)</b>	sodium chloride, water for injections

DBL Leucovorin Calcium Injection 15 mg/2 mL contains 8.1 mg/mL of sodium chloride.

DBL Leucovorin Calcium Injection 50 mg/5 mL and 300 mg/30 mL contains 8.5 mg/mL of sodium chloride.

### **What DBL Leucovorin Calcium Tablet contains**

<b>Active ingredient (main ingredient)</b>	calcium folinate hydrate
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<b>Other ingredients (inactive ingredients)</b>	lactose, microcrystalline cellulose, magnesium stearate
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Each DBL Leucovorin Calcium Tablet contains 141.4 mg of lactose monohydrate.

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What DBL Leucovorin Calcium looks like**

DBL Leucovorin Calcium Injection is a clear, straw to pale yellow coloured solution free from visible particulate matter.

DBL Leucovorin Calcium Tablet is light yellow, round, flat with a line and engraved with the letters CF.

## **Australian Registration Number**

DBL Leucovorin Calcium Injection 15 mg/2 mL, AUST R 16351.

DBL Leucovorin Calcium Injection 50 mg/ 5 mL, AUST R 42148.

DBL Leucovorin Calcium Injection 300 mg/ 30 mL, AUST R 116688.

DBL Leucovorin Calcium Tablet 15 mg, AUST R 16364.

## **Who distributes DBL Leucovorin Calcium**

Pfizer Australia Pty Ltd

Sydney NSW.

Toll Free Number: 1800 675 229.

[www.pfizermedinfo.com.au](http://www.pfizermedinfo.com.au).

This leaflet was prepared in April 2022.